

REMARKS

Status of the Claims:

Claims 1-25 were originally submitted and were canceled by Preliminary Amendment filed October 16, 2003 and Supplementary Preliminary Amendment filed June 29, 2004. Claims 26-32 were introduced by these preliminary amendments and are currently pending. Claims 26-32 stand rejected. Claim 27 is currently amended; no new matter is introduced.

Reconsideration and withdrawal of the rejection is respectfully requested in light of the following Remarks.

Rejection of Claims 26-32

Claims 26-32 stand rejected under 35 U.S.C. §112 as allegedly being indefinite. Examiner requests clarification of the claim term “nervous strain” in claim 26.

i) Claim 26

Applicants respectfully submit that the term “nervous strain” is well known by one of ordinary skill in the psychology field and there are sufficient teachings in the prior art. For example, The Royal Bank of Canada describes in November of 1947 the psychological ailment: “...while modern invention has relieved physical drudgery it has increase the nervous strain...” (page 2, right column, last paragraph). Nicola Cherry discloses “nervous strain at work” and correlates “nervous strain” to working people’s predisposition to anxiety and to the day-to-day activities in their job. (J. Occup. Psychol. 1978, 51, 259-270). Christopher Tennant discloses “work-related stress and depressive disorder” and further discloses that work tasks made a significant contribution to “nervous strain” (J. Psychosomatic Research 51 (2001) 697-704. Copies of this prior art are submitted herewith.

U.S. Patent No. 6,582,736 discloses a therapeutic oil composition containing several essential oils useful for treating nervous strain. U.S. Pat. Nos. 4,628,056 and 6,664,262 disclose treating nervous strain with non-sedative barbituric acid derivatives. U.S. Patent Office has consistently held these patent applications relating “nervous strain” to satisfy the 35 U.S.C. § 112 requirement and hence patentable.

Applicants respectfully submit that the term “nervous strain” has a dictionary meaning of “nervousness resulting from mental stress” (*See*, e.g., www.hyperdictionary.com; www.wordwebonline.com; www.thefreedictionary.com).

Because the term “nervous strain”: i) is well known in the pertinent art; ii) there are sufficient teachings in the prior art; and iii) has a dictionary meaning, applicants submit that

the term satisfies the statutory requirements of 35 U.S.C. § 112, second paragraph. Applicants respectfully request that the rejection be withdrawn.

ii) Claim 27

Examiner requests clarification as to whether the composition of claim 27 comprises a compound and salt and carrier, or a compound or salt thereof.

Applicants have amended claim 27 to better clarify the Applicants' intention to claim a pharmaceutical composition comprising: a) at least one compound from a Markush selection of N-methoxymethyl-5,5-diphenylbarbituric acid and a pharmaceutical acceptable salt of N-methoxymethyl-5,5-diphenylbarbituric acid; and b) a pharmaceutical acceptable carrier. The amendment does not narrow the claim scope and shall overcome the claim rejection.

Objection to Claims 28 and 29

Examiner objects to claims 28 and 29 under 37 C.F.R. 1.75(c) as being of improper dependent form for allegedly failing to further limit the subject matter of a previous claim. Examiner alleges that the only compound in claim 27 is N-methoxymethyl-5,5-diphenylbarbituric acid.

Applicants point out that the Examiner is incorrect to state that "the only compound in claim 27 is N-methoxymethyl-5,5-diphenyl-barbituric acid." Contrary to Examiner's assertion, claim 27 recites N-methoxymethyl-5,5-diphenylbarbituric acid and a pharmaceutical acceptable salt of N-methoxymethyl-5,5-diphenylbarbituric acid. As such, claims 28 and 29 are proper dependent claims (*See*, MPEP § 2173.05(h)) and the claim objection is moot.

Objection to Claims 30-32

Examiner objects to claims 30-32 under 37 C.F.R. § 1.75 as allegedly being substantial duplicates of claims 27-29 in the present application.

Applicants submit that claims 30-32 further limit respective claims 27-29 by reciting the amount of compound in the pharmaceutical composition. As stated above, claims 27-29 are not substantial duplicates. Dependent claims 30-32, which further limit claims 27-29, cannot be substantial duplicates. Applicants respectfully request that the objection be withdrawn.

Double Patenting

Claims 26-32 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Pat. No. 6,664,262 patent (the '262 patent).

Without agreeing to the substantive basis of the Examiner's rejection, and in order to expedite the prosecution, applicants will submit a Terminal Disclaimer in compliance with 37 CFR § 1.321(c) upon recognition of the allowability of any pending claims. Applicants respectfully point out that the present patent application and the '262 patent are commonly owned.

For at least the reasons set forth herein, Applicants respectfully submit that all of the Examiner's rejections and objections have been overcome and all the pending claims are allowable.

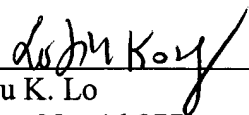
CONCLUSION

Accordingly, withdrawal of the rejection and allowance of the present application are respectfully requested. The Examiner can reach undersigned at (914) 345-9001 (x6858) when he takes this application up for further action.

Respectfully submitted,

TARO PHARMACEUTICAL U.S.A., INC.

Dated: November 3, 2004

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